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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,961	09/18/2001	Minter H. Dopson	01-2224	8520
27530	7590	03/23/2005	EXAMINER	
NELSON MULLINS RILEY & SCARBOROUGH, LLP 1320 MAIN STREET, 17TH FLOOR COLUMBIA, SC 29201			SCHWADRON, RONALD B	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 03/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/954,961

Applicant(s)

DOPSON, MINTER H.

Examiner

Ron Schwadron, Ph.D.

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1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 21 and 22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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1. Applicant's election without traverse of bird/T cell antigen in the reply filed on 12/24/2004 is acknowledged.

2. Claims 1-9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/24/2004.

Regarding applicants comments and the nonelected species, the antigen of claim 1 as described/exemplified in the specification appears to not encompass antigens consisting of only a T cell epitope.

3. Claims 21,22 are under consideration.

4. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e).

An application in which the benefits of an earlier application (eg. 60/233400) desired must contain a specific reference to the prior application(s) in the first sentence. A statement reading "This application claims priority to Provisional Application Serial No. -----, filed -----" should be entered following the title of the invention or as the first sentence of the specification.

It is noted that the application as originally filed contained a priority claim to the aforementioned application in the oath.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 21,22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the recitation of "non-mammalian source animal" in claim 21 or 22. While the specification discloses use of birds to produce transfer factor, there is no disclosure in the specification as originally filed of the scope of the claimed invention which uses the genus of "non-mammalian source animals". The aforementioned limitation reads on the use of egg laying nonmammals such as reptiles or fish, yet the use of said animals in the claimed method is not disclosed in the specification as originally filed.

There is no support in the specification as originally filed for the recitation of "antigenic agent " that will "elicit a t cell mediated immune response" in claim 21 or 22. Said limitation encompasses the use of peptides consisting of only a T cell epitope or epitopes, yet there is no disclosure in the specification as originally filed of the use of such peptides in the claimed method. Similarly, there is no disclosure in the specification as originally filed that the antigen used should elicit a t-cell mediated response.

There is no support in the specification as originally filed for the recitation of "includes transfer factor molecules having molecular weights of about 4,000 Da to about 5,000 Da" in claim 21 or 22.. The specification does not disclose the claimed method wherein the transfer factors are of the molecular weights of about 4,000 Da to about 5,000 Da.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21 and 22 are indefinite in the recitation of "4,000 Da to about 5,000 Da" in the absence of a recitation of the technique used to establish the molecular weight (such as SDS PAGE gel electrophoresis, etc). Different techniques have different standard errors and varying degrees of accuracy so the inclusion of the method used to establish the molecular weight is necessary to evaluate what the recited molecular

weight means and encompasses.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 21,22 are rejected under 35 U.S.C. 102(b) as being anticipated by Tokoro (US Patent 5,080,895) as evidenced by Zhang et al and Lipford et al.

Tokoro teaches a method of making transfer factor specific for a pathogen wherein the transfer factor includes the particular transfer factor recited in the claims (because the method of Tokoro recovers transfer factor less than 10,000 mw)(see abstract and columns 5-7). The transfer factor is purified from the eggs of an immunized hen (see columns 5-7). Thus, the transfer factor containing eggs are first collected from the immunized hen. The hens can be immunized with a specific virus to produce an antiviral transfer factor (see column 4, penultimate paragraph). It is an inherent property that viral antigens contain T cell epitopes that would stimulate T cell responses (such as CTL, see Zhang et al., first column, page 2217, first paragraph). Example II indicates that the eggs would be harvested after several weeks. A T cell mediated immune response would have inherently occurred by this timepoint (see Lipford et al. page 1214, second column, last paragraph which indicates that a CTL response can be detected as early as four days post immunization.).

11. No claim is allowed.


12. Regarding applicants request for an interference, there are no allowed claims in the instant application for the reasons stated above.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RONALD B. SCHWADRON
PRIMARY EXAMINER
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Art Unit 1644